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EXTRACORPOREAL MAGNETIC INNERVATION (EXMI) IN THE TREATMENT OF URINARY INCONTINENCE IN WOMEN - A REVIEW OF RESEARCHES

Weber-Rajek Magdalena[1], Agnieszka Radzimińska[1], Marta Podhorecka[2]

[1]Nicolaus Copernicus University in Torun, Collegium Medicum in Bydgoszcz, Department of Physiotherapy, Division of Principles of Physiotherapy, Bydgoszcz, Poland; [2]Nicolaus Copernicus University in Torun Collegium Medicum in Bydgoszcz, Department of Geriatrics, Bydgoszcz, Poland.

ABSTRACT

Background: According to the World Health Organization and the International Continence Society, urinary incontinence is defined, in an objective manner, as a lack of control over urination. In women urinary incontinence is a common problem in peri- and postmenopausal period and a general symptom associated with pregnancy as well. Physical methods are used in the conservative treatment of urinary incontinence. A relatively new physical method used in the treatment of urinary incontinence is Extracorporeal Magnetic Innervation.

Aim: The aim of this study is a systematic review of researches assessing the efficacy of magnetic therapy in the treatment of urinary incontinence in women.

Methods: Clinical studies searching was based on a detailed report in accordance to the guidelines of the Cochrane Collaboration. The following databases were searched through: Pub Med., Medline, Embase, The Cochrane Library (Central). The key words were: urinary incontinence, Extracorporeal Magnetic Innervation, ExMI, magnetic stimulation and related expressions. The databases from 1998 till the year 2016 were searched.

Results: The above keywords were found in the databases of 27 studies assessing the efficacy of ExMI in the treatment of UI in women. These studies were evaluated by two independent reviewers who selected two studies that met the established criterion of the inclusion in the review.

Conclusion: Magnetic Stimulation used in the treatment of urinary incontinence is a non-invasive, painless and comfortable for the patient method, and therefore there is a need for studies with a well-designed research protocol

Key Words: Extracorporeal Magnetic Innervation, Urinary incontinence

INTRODUCTION

According to the WHO (World Health Organization) and the ICS (International Continence Society), urinary incontinence (UI) is defined, in an objective manner, as a lack of control over urination [1]. In women urinary incontinence is a common problem in peri- and postmenopausal period and a general symptom associated with pregnancy as well. Epidemiological data on the prevalence of the disease is vague, ranging from 7% to 53% [2,3]. According to the Standarisation Steering Comitee ICS there are three main types of NTM: stress (SUI -stress urinary incontinence), urgency (UUI-urge urinary incontinence and mixed (MUI-mixed urinary incontinence) [4]. Physical methods are used in the conservative treatment of urinary incontinence. The most commonly used means is electrical stimulation, which was first applied in 1963 by Cadwell [5]. Electrical stimulation strengthens the muscles of the pelvic floor - contraction of the external urethral sphincter, the increase of intraurethral pressure and the contraction of the levator ani that contributes to the elevation of the bladder neck and to the extension of the initial urethra [6]. Additionally, triggered impulses running through the nerves in labia segments S2-S4 of spinal cord contribute to better functioning of that reflex route [6]. Although the efficacy of electrical stimulation is confirmed by numerous scientific studies, not all patients opt for this

Corresponding Author:
Weber-Rajek Magdalena; PhD Magdalena Weber-Rajek, Skłodowskiej-Curie street 35/206, 85-733 Bydgoszcz; Ph: 602478253;
E-mail: magdawr69@gmail.com

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form of therapy (discomfort, excessive psychological stress [6,7,8]. A relatively new physical method used in the treatment of urinary incontinence is Extracorporeal Magnetic Innervation (ExMI). Electromagnetic pulsing technology for pelvic floor muscle stimulation was approved as treatment for UI by the U.S. Food and Drug Administration in June 1998 [9] and by the European Commission in January 2011 [10].

It is a completely non-invasive and painless method. The patient sits on a specially designed treatment chair, where a therapeutic head is attached. It produces magnetic field penetrating the organs of the pelvis minor [9,11]. The magnetic field acts directly on the motor fibers of pudendal and visceral nerves. The activation of sodium-potassium pump and the regulation of motor neurons depolarization cause pulses priming in neuromuscular plates that force muscle contraction in the innervated area [9,11].

The aim of this study is a systematic review of researches assessing the efficacy of magnetic therapy in the treatment of urinary incontinence in women.

METHOD

Clinical studies searching was based on a detailed report in accordance to the guidelines of the Cochrane Collaboration [12]. The following were taken into account: the criteria of inclusion of the research for the review, search strategy and the method of tests selection.

The analysis was based on the clinical studies that met the following criteria:population: women with various forms of urinary incontinence;

- intervention: a therapy using Extracorporeal Magnetic Innervation with the parameters of magnetic field stated;
- methodology: randomized controlled clinical studies; clinical studies with blind, clinical studies with the control group;
- endpoints: efficacy - evaluation of bladder function, quality of life, safety (side effects).

The following databases were searched through: Pub Med., Medline, Embase, The Cochrane Library (Central). The key words were: urinary incontinence, Extracorporal Magnetic Innervation, ExMI, magnetic stimulation and related expressions. The databases from 1998 (the year when electromagnetic technology for pelvic floor muscle stimulation was approved as treatment for UI by the U.S. Food and Drug Administration) till the year 2016 were searched through.

Study selection and data extraction:

The above keywords were found in the databases of 27 studies assessing the efficacy of ExMI in the treatment of UI in women. These studies were evaluated by two independent reviewers who selected two studies that met the established criterion of the inclusion in the review.

RESULTS

221 patients took part the studies analyzed for the purpose of this review. 136 women underwent the therapy of ExMI and 85 were in a sham group. Gilling et al. [13] examined 70 women with SUI that had been randomly divided into two groups. The first group (n = 35) was treated with ExMI (3 sessions per week, for 6 weeks), the second group (n = 35) was sham. The following magneto fields parameters were used: 10 Hz for 10 minutes, three minute brake, and then at 50 Hz for 10 minutes. The intensity of electromagnetic stimulation was adjusted to the maximum value tolerated by the patient. The sham therapy group had the same treatment plan, however a thin deflective aluminium plate was put in the chair. That prevented the magnetic field penetration into the patient. Moreover, the noise and sensation similar to proper active session were produced. The women were not told which treatment they had undergone till the end of the study. In order to assess the therapy efficacy the following means were applied: The Urinary Incontinence Quality of Life Scale (I-QOL), King's Health Questionnaire (KHQ), 3-day bladder diary, 24-h pad-test, the number of pads used and PFM strength and perineometry. The women were re-examined 8 weeks after they had started the treatment, then at 6 months they were evaluated with the use of a diary, pad-test and questionnaires. No disturbances were noticed and sent to the data monitoring centre.

The results showed that, in the total group of 70 patients there were significant improvements measured, both in primary and secondary examinations. Furthermore, in the group that had undergone the active therapy, significant improvements were noticed in primary and secondary measures in comparison to baseline measure. At 8 weeks, the mean (SD) values for the 20-min pad-test, the 24-h pad-test, the number of pads/day; the I-QOL score and KHQ score were improved. However, no statistically significant difference was noticed when both groups' improvements had been compared. In women with poor pelvic floor contraction at the first examination there was a significant reduction in the 20-min pad-test leakage in comparison to the sham group. As a result of examinations the authors concluded that the whole applied therapy was not more effective than the sham treatment in the group described above. However, in women unabled to perform an adequate pelvic floor muscle contraction, significant improvements occurred in provocative pad testing, in comparison to the sham treatment.

Yamanishi et al. [14] examined the group of 151 women with SUI and MUI. The women were randomly assigned to two groups: treated group (n = 101) and sham group (n = 50). The treatment was carried out twice a week for 6 weeks. The treatment group used the following parameters of magneto fields: 10 Hz, 560 mT, pulse duration of 300 microseconds, the time of the session - 25 minutes. The maximum intensity of sham stimulation was set at a lower level in comparison to the active stimulation. In that situation no stimulation effect would appear (114 mT, 300 μs, 1 Hz, 5-s „on" 5-s „off" pulsing manner). In order to assess the efficacy of the therapy the following factors were considered: changes in the number of urinary incontinence episodes per week stated in the patient's bladder diary, changes in the mean number of voids per 24 h, urgency episodes per 24 h, mean voided volume per micturition (ml) and maximum voided volume per micturition (ml) in the bladder diary, Overactive Bladder Symptoms Score (*OABSS*), International Prostate Symptom Score, Quality of life index (IPSQOL index). Differences from baseline in the active and sham group, were in leaks/week ($p = 0.038$), in number of urgency episodes/24 h ($p = 0.011$), in mean voided volume ($p = 0.0056$). Two types of side effect were observed – diarrhoea and constipation.

DISCUSSION

The results of this review show that there is a need for studies with a well-designed research protocol, that evaluates ExMI efficacy in the treatment of UI. Similar conclusions were drawn by Lim et al. [10] who noticed the lack of randomized, sham-controlled trials and the lack recommendations on the use of magnetic stimulation for stress urinary incontinence. Lim et al. [10] suggested the following research protocol (Table 1).

Table 1: The research protocol - Magnetic stimulation for stress urinary incontinence by Lim et al. [10]

Type of study	**randomized, double-blind, sham-controlled parallel-group**
Examined group	120 subjects with SUI assigned in a 1:1 to either active or sham group
Inclusion criteria	– female aged 21 years and older; – demonstration of urine leak on coughing at a bladder volume of approximately 200 to 250 ml; – International Consultation on Incontinence Questionnaire for Urinary Incontinence Short Form (ICIQ-UI-SF) score of at least 6 points (range: 0–21); – patients must be able and agree to carry out 1-hour pad test and; – voluntary participation and signing of the written consent after being informed.
Exclusion criteria	– patients with UUI, MUI, overflow UI; – acute severe infections; – severe cardiac arrhythmia; – cardiac pacemaker or other implanted metallic devices; – neurologic conditions (e.g., stroke, epilepsy, Parkinson's disease, multiple sclerosis); – random blood sugar above 10 mmol/L; – pregnancy or active trying to conceive; – previous surgery for SUI; – pelvic or gynecological surgery for less than 3 weeks or within next 8 weeks; – previous treatment with MS; – history of pelvic irradiation; – concurrent medications with α-adrenergic antagonists (e.g., terazosin, tamsulosin, doxazosin), diuretics, serotonin-norepinephrine reuptake inhibitors or any other medications known to worsen incontinence; – stage III or IV of pelvic organ prolapse according to Pelvic Organ Prolapse Quantification System ; – severe urethral sphincter weakness and/or defect; – suspected urethral and/or vesical fistula; – urinary tract infection or hematuria; and/or – postvoid residual volume greater than 200 ml.

Therapy parameters	**Active magnetic stimulation** – 2 sessions of magnetic stimulation per week for 8 weeks; – magnetic field parametrs: 50 Hz, "on" – 8 s, "of" – 4 s, the intensity increased from 20% to100%; **Sham magnetic stimulation** – using the same equipment and the same parameters as in the active group, but a magnetic coil was leaned at the angle of 22° and it induced magnetic field of lower intensity: starting at 20% of intensity at the first session, and subsequently increased by 20% after every five sessions, rising to a maximum of 60% of intensity.
Study results	**Primary outcome** – International Consultation on Incontinence Questionnaire for Urinary Incontinence Short Form (ICIQ-UI-SF). The primary criterion for response is defined as having a 5-point or greater reduction in the ICIQ-UI-SF score (score range: 0–21) from baseline to 8 weeks; **Secondary outcomes** – cure, – stress urinary incontinence-related symptoms (incontinence episode frequency, urine loss in 1-hour pad test, – pelvic floor muscle strength); – health-related quality of life: • Patient Global Impression of Improvement; International Consultation on Incontinence Questionnaire (ICIQ) -Lower Urinary Tract Symptoms Quality of Life; • EuroQol five dimensions questionnaire (EQ-5D).
The safety of magnetic stimulation	cost-efficacy analysis using patient-reported outcomes

CONCLUSION

Magnetic Stimulation used in the treatment of urinary incontinence is a non-invasive, painless and comfortable for the patient method, and therefore there is a need for studies with a well-designed research protocol.

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